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January 3, 2024

Honorable Nicholas G. Garaufis, District Judge, Eastern District of New York

Re: Exactech Polyethylene Orthopedic Products Liability Litigation 22-md-03044-NGG-MMH

Dear Judge Garaufis:

Pursuant to the Court's Order (Dkt. 494), we write on behalf of Exactech to identify issues the Court should consider in reviewing the proposed Bellwether Trial Order (Dkt. 475-2) and setting initial bellwether trials in a manner that can expeditiously lead to disposition and resolution of the vast majority of cases in this MDL.

A. The Court needs adequate time after the close of expert discovery to address potentially dispositive pretrial motions, especially those focused on the issue of shelf-life, that will streamline the entire MDL.

A primary purpose of an MDL is to allow the parties to test key theories and defenses in "bellwether" trials and evaluate the strengths and weaknesses of their evidence. Fallon, et al., *Bellwether Trials in Multidistrict Litigation*, 82 Tul. L. Rev. 2323, 2337-38 (2008), attached as **Ex. A**. A further purpose of an MDL is to have one federal judge rule on major issues that cut across all cases – rulings that will travel with all cases on remand or help lead to resolution without remand. Rule 702 motions addressing expert opinions on defect and general and specific causation are the most crucial of these rulings.

1. The Court needs sufficient time to decide critical Rule 702 motions, including motions regarding common theories of defect and causation.

As the Manual for Complex Litigation recognizes, the decision to admit or exclude testimony under Rule 702 significantly impacts the ability of parties sharing commons claims and theories to prevail in an MDL. Manual for Complex Litigation (Fourth), attached as **Ex. B**, at § 23.1. These decisions often impact all cases in an MDL, inform the parties about the merits of hundreds (and often thousands) of individual cases, and help lead to overall resolution in an efficient manner. *See* Fallon at 2337-38.

That is particularly true in this MDL. A critical overarching scientific issue that will require Rule 702 adjudication is whether implants with low-shelf life are impacted by the packaging non-conformity. Plaintiffs have alleged, and will argue, that the "improper shelf-life" of Exactech's knee polyethylene inserts "coupled with the failure to barrier package the devices to prevent oxidation, greatly increased the risk of oxidation and embrittlement of the [polyethylene] devices." Am. Master Compl. (Dkt. 164) at ¶¶ 515-519.

However, as the Court may recall from Science Day, the science demonstrates that the bag nonconformity has no impact on the risk of oxidation and the clinical success of Exactech's knee polyethylene in cases with low shelf-life. This matters because the vast majority of knee cases in this MDL – approximately 90% based on currently available data – have a shelf life of five years or less.

In fact, available data also demonstrates that approximately 40% of cases have a shelf life of ***one year or less***. This means that whether the bag nonconformity could have had any impact on the clinical success of Plaintiffs' Exactech devices will be a threshold Rule 702 determination in almost all the cases in this MDL – a determination that could result in dismissal or a significant narrowing of the relevant issues in the vast majority of cases and, as a result, have a significant impact on resolution.

Given the significance and breadth that the issue of shelf-life has on this MDL, as well as the distribution of the cases that have been filed so far, the Court should select low shelf-life cases as bellwethers so that it can address the threshold shelf-life issue up front and implement its rulings across the vast majority of the MDL pool. By selecting representative low shelf-life cases as bellwethers and adjudicating the admissibility of common scientific theories related to shelf life and the bag nonconformity under Rule 702, the Court will provide the best opportunity to resolve common claims and large portions of this MDL on the front end without the need for multiple trials, through mass dismissals, screening orders, and/or summary judgment. *See, e.g.,* Law 360, Zimmer Knee MDL Shrinks Further Under Judge's Wary Eye, https://www.law360.com/articles/840440. This practical approach will advance the overarching goal of the bellwether process – to "accelerate" the MDL and "effectuate an actual culmination to the litigation" as efficiently and timely as possible. Fallon at 2325, 2344. It is also a common approach taken by MDL courts in this Circuit.

For instance, in the Zimmer M/L Taper Hip MDL pending before Judge Paul Crotty, the plaintiffs pursued common liability theories and disclosed a common expert to offer general defect opinions in the first four bellwether cases. After receiving substantial Rule 702 briefing, Judge Crotty exercised his gatekeeping function and excluded the testimony of plaintiffs' common defect expert in its entirety, finding that "there [was] too large a gap between the data she relie[d] upon and the conclusions she reache[d]." *In re Zimmer M/L Taper Hip Prosthesis Prod. Liab. Litig.*, 2021 WL 3475681, at *7 (S.D.N.Y. Aug. 6, 2021). As a result of this decision, the Court stayed the remaining bellwether cases, and soon thereafter the parties reached a global settlement agreement that resolved 99% of related cases within just three years of the MDL's creation. Other MDL courts within this Circuit have similarly used common Rule 702 rulings to dispose of large portions, and in some instances entire inventories, of product liability MDLs. *See, e.g., In re Mirena IUD Prod. Liab. Litig.*, 202 F. Supp. 3d 304 (S.D.N.Y. 2016), *aff'd*, 713 F. App'x 11 (2d Cir. 2017) (granting defendants' motion for summary judgment and disposing of other cases after plaintiffs' general causation experts were excluded under Rule 702); *In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II),* 387 F. Supp. 3d 323 (S.D.N.Y. 2019), *aff'd,* 982 F.3d 113 (2d Cir. 2020) (same); *In re Acetaminophen—ASD-ADHD Products Liability Litigation*, 2023 WL 8711617 (S.D.N.Y. Dec. 18, 2023) (excluding plaintiffs' general causation expert in approximately 600 cases and effectively ending the entire MDL).

In short, resolution of the threshold shelf-life issue is critical and equally important to both sides, and using the first bellwethers to assess whether the predominant theory of defect satisfies Rule 702 in the vast majority of cases will lead to an efficient disposition of the MDL as a whole.

To that end, Exactech suggests that the Court (a) select low shelf-life cases as bellwethers, as they are the most representative of the entire pool of cases within the MDL; (b) build in at least four months between the close of expert discovery and the first bellwether trial to address the significant anticipated Rule 702 briefing; and (c) include a provision in the Bellwether Trial Order to make it clear that any

Rule 702 and other pretrial rulings regarding common theories of defect and causation (e.g., shelf life, evidence of the recall, etc.) apply to all cases in this MDL.

2. The Court also needs sufficient time to decide motions *in limine*, including motions regarding the admissibility of regulatory evidence.

The four months Exactech suggest building into the schedule between the close of expert discovery and the first bellwether trial will also allow the Court to adequately weigh critical motion *in limine* decisions including, for example, the admissibility of regulatory evidence in bellwether trials. The Court will specifically need to consider motions *in limine* regarding the admissibility of evidence relating to (a) Exactech's voluntary recall; (b) foreign regulatory activity; and (c) the regulatory history of the Exactech products at issue, among other motions. These issues have been addressed by multiple courts, including MDL courts, across the country. *See, e.g., Bilenky v. Ryobi Ltd*., 2014 WL 12591940, at *6 (E.D. Va. Oct. 22, 2014) (evidence of a product recall inadmissible); *Sadio v. MacLaren USA, Inc.,* 2014 WL 6487776, at *1 (S.D.N.Y. Nov. 13, 2014) (same); *In re Viagra Prods. Liab. Litig*., 658 F.Supp.2d 950, 965 (D. Minn. 2009) (evidence of foreign regulatory evidence inadmissible); *In re Seroquel Prods. Liab. Litig*., No. 06–MD–1769, 2009 WL 223140, at *6 (M.D. Fla. Jan. 30, 2009) (same); *Kelley v. C.R. Bard, Inc*., 2023 WL 2565853, at *2 (N.D. Ga. Mar. 17, 2023) (evidence that medical device was cleared by FDA admissible and relevant to plaintiffs' product defect claims and request for punitive damages).

B. Trying cases involving patients from HSS will not expedite the resolution of this MDL.

During the status conference on December 20, 2023, the Court indicated it had a desire to try a local Eastern District of New York case as the first bellwether in this MDL, possibly given practical and logistical convenience. Given outlier characteristics of Eastern District cases involving the Hospital for Surgery ("HSS"), the Court should be wary of (i) selecting an HSS case as an initial bellwether or (ii) weighing the results of any HSS case too heavily.

First, the majority of MDL plaintiffs (at least 60%) were ***not*** treated at HSS. Second, HSS surgeons' experiences with the MDL products are not reflective of the products' performance nationally; while HSS surgeons account for only about 10% percent of the recalled Exactech knees implanted by U.S. surgeons, more than 35% of lawsuits involve HSS patients. Thus, while trying a local case may be logistically attractive, cases involving HSS will not reflect the inventory of U.S. cases, or the experiences of U.S. surgeons and patients, as a whole.

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In sum, while Plaintiffs will rely heavily on the bag nonconformity and recall to prove their cases, there are significant threshold factual, legal, and scientific issues that need to be decided prior to the first bellwether that could expedite this MDL. Exactech respectfully requests that the Court give serious consideration to these critical pretrial issues before entering the proposed Bellwether Trial Order (Dkt. 475-2) and setting initial bellwether trials.

Respectfully submitted,

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cc: All Counsel of record (*via ECF*)